K080950

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# Summary of Safety and Effectiveness STIWELL med4

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## C Product Name/ Classification Name:

Common or Usual Name: Powered Muscle Stimulator
Proprietary or Trade Name: STIWELL med4
Model Number: 900101S

| Class | Regulation No. | Device Classification Name | Product Code | Speciality |
|---|---|---|---|---|
| II | 890.5850 | Stimulator, Muscle, Powered | IPF | Physical Medicine |
| II | 882.5890 | Stimulator, Nerve, Transcutaneous, For Pain Relief | GZJ | Neurology |
| II | 882.5050 | Device, Biofeedback | HCC | Neurology |
| II | 882.5810 | Stimulator, Neuromuscular, External Functional | GZI | Neurology |
| II | 876.5320 | Stimulator, Electrical, Non-Implantable, For Incontinence | KPI | Gastroenterology/ Urology |

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**D Predicate Devices:**

| 510(k) No. | Predicate Device | Manufacturer | Regulation Number | Product Code(s) | Clearance Date |
|---|---|---|---|---|---|
| K032954 | Elpha Models II 500, II 1000, II 2000, II 3000 A | Danmeter A/S | 890.5850 | IPF, GZJ | 08/09/2004 |
| K053434 | Myotrac Infinity Electrical Stimulator | Thought Technology Ltd. | 876.5320 | KPI, HCC, IPF | 03/15/2006 |
| K040849 | Mentamove | Cole & Associates | 890.5850 | IPF, HCC | 10/01/2004 |
| K940301 | Compex 2 | Biodex Medical Systems, Inc. | 890.5850 | IPF, GZJ | 12/28/1994 |
| K032988 | Elpha 4 Conti | Danmeter A/S | 876.5320 | KPI | 12/03/2003 |
| K031900 | Handmaster | Ness-Neuromuscular Electrical Stimulation Systems | 882.5810 | GZI | 08/08/2003 |

**E Description:**

The STIWELL med4 is powered by rechargeable batteries. It has four stimulation channels and two EMG measurement channels.

The STIWELL med4 is intended for stationary use in a hospital as well as home use by the patient. The physician/therapist has the flexibility to adjust the programs and monitors the progress of the therapy. Statistics regarding the completed treatments can be retrieved from the STIWELL med4 and from the PC.

In order to gain a proper understanding of STIWELL med4, it is important to read the manual before beginning to use the STIWELL med4.

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## F Substantial Equivalence:

Powered Muscle Stimulator:

| Characteristics/ Specific. | New Device | Predicate Device | Predicate Device | Predicate Device | Predicate Device |
|---|---|---|---|---|---|
| ***Basic Unit Chracteristics*** | | | | | |
| 510(k) Number | K080950 | K032954 | K053434 | K040849 | K940301 |
| Manufacturer | Otto Bock | Danmeter A/S | Thought Technology Ltd. | Mentamove North America, LCC | Compex SA |
| Device Name, Model | STIWELL med4 | Elpha II3000 | Myotrac Infinity | Mentamove | Compex 2 |
| Power Source(s) | Battery Pack Li-Ion 11,1V | Battery NMH or Alkaline 9V | Battery Pack NiMH rechargeable | Battery Pack NiMH rechargeable | Battery Pack NiMH 7,2 V |
| Method of Line Current Isolation | Medical Class II Power Adapter – Mascot (12,6VDC-15,1W) | N/A | Medical Class II Power Adapter (6VDC-15W) | Battery Charger (6VDC-2,1W) | Battery Charger (11VDC-7,2W) |
| Patient Leakage Current (normal condition) | N/A (Battery) | N/A (Battery) | N/A (Battery) | N/A (Battery) | N/A (Battery) |
| Patient Leakage Current (single fault condition) | N/A (Battery) | N/A (Battery) | N/A (Battery) | N/A (Battery) | N/A (Battery) |
| Number of Output Modes | 1 | 1 | 1 | 1 | 1 |
| Number of Output Channels | 4 | 2 | 2 | 1 | 4 |
| Number of EMG (input) Channels | 2 | N/A | 2 | 1 | N/A |
| EMG sensitivity | 1µV | N/A | <0,1µV | 1µV | N/A |
| EMG Sampling Rate | 3kHz | N/A | 2,048kHz | Unknown | N/A |
| EMG detection (bipolar/ monopolar) | Bipolar | N/A | Bipolar | Bipolar | N/A |
| EMG range (µV) | 1-2000µV | N/A | 0-2000µV | 2-2000µV | N/A |
| EMG bandwidth | 70-480Hz | N/A | 10Hz-1kHz | Unknown | N/A |
| EMG signal processing (eg. RMS) | AVR (Average Rectified Value) | N/A | RMS (Root Mean Square) | Unknown | N/A |
| Synchronous or Alternating? | Alternating | Unknown | Alternating | N/A | Synchronous |
| Method of Channel Isolation | Transformer, Inductive couplers | Unknown | Unknown | Unknown | Transformer |
| Regulated Current or Regulated Voltage? | Regulated Current | Regulated Current | Regulated Current | Regulated Current | Regulated Current |
| Software/Firmware/ Microprocessor Control? | Yes | Yes | Yes | Yes | Yes |
| PC Software? | Yes | No | Yes | No | No |
| Automatic Overload Trip? | Yes | Yes | Yes | Yes | Yes |
| Automatic No-Load Trip? | Yes | Yes | Yes | Yes | Yes |
| Automatic Shut Off? | Yes (10min) | Yes | Unknown | Unknown | Unknown |
| Patient Override Control? | Yes (Stop Button) | Yes | Yes | Yes | Yes |
| Indicator Display: On/Off Status? | Yes | Yes | Yes | Yes | Yes |
| Indicator Display: Low Batt.? | Yes | Yes | Yes | Yes | Yes |
| Indicator Display: Voltage/Current Level? | Yes | Yes | Yes | Yes | Yes |
| Timer Range [minutes] | 2 – 120min | 5 – 95min and cont. | 1 – 120min | Unknown | 3 – 64min |
| Compliance with Voluntary Standards? (if yes, specify) | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-2-10 | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-2-10 | Unknown | Unknown | Unknown |
| Compliance with 21 CFR 898? | Yes | Unknown | Unknown | Unknown | Unknown |
| Weight | 440g | 158g | 330g | Unknown | 420g |
| Dimensions (WxHxD) in [mm] | 175x95x30 | 114x80x31 | 102x152x51 | Unknown | 148x80x30 |
| Housing Material and Constr. | Plastics | Plastics | Plastics | Plastics | Aluminium |
| ***Output Specifications*** | | | | | |
| Waveform | Biphasic symmetrical | Biphasic asymmetrical | Biphasic asymmetrical | Biphasic symmetrical | Biphasic symmetrical |
| Shape | Rectangular | Rectangular with discharge | Rectangular with discharge | Rectangular | Rectangular, Triangular |
| Maximum Output Voltage (500Ω) | 50V | 50V | 50V | Unknown | 50V |
| Maximum Output Voltage (2kΩ) | 115V | 164V | Unknown | Unknown | 200V |
| Maximum Output Voltage (10kΩ) | N/A | Unknown | Unknown | Unknown | N/A [1] |
| Maximum Output Current (500Ω) | 100mA | 100mA | 100mA | Unknown | 100mA |
| Maximum Output Current (2kΩ) | 58mA | 82mA | Unknown | Unknown | 100mA |
| Maximum Output Current (10kΩ) | N/A | Unknown | Unknown | Unknown | N/A |
| Pulse Width (specify units) | 50µs – 400µs | 100µs – 400µs | 50µs – 400µs | 320µs | 15µs – 999µs |
| Frequency [Hz] | 1 – 140Hz | 2 – 100Hz | 2 – 100Hz | 3,1kHz CF, 33Hz AMF | 1 – 200Hz |
| For interferential modes only: Beat Frequency [Hz] | N/A | N/A | N/A | N/A | N/A |
| For multiphasic waveforms only: Symmetrical phases? | N/A | N/A | N/A | N/A | N/A |
| For multiphasic waveforms only: Phase Duration (including units): | N/A | N/A | N/A | N/A | N/A |
| Net Charge [µC per pulse]: (500Ω) | 0µC<br>Same positive and negative impulse | 0µC<br>Output capacitor | 0µC<br>Output capacitor | 0µC<br>Same positive and negative impulse | 0µC<br>Same positive and negative impulse |
| Maximum Phase Charge [µC] (500Ω) | 40µC | 40µC | 60µC | Unknown | 80µC |
| Maximum Current Density [mA/cm²] (500Ω) | 12,5mA/cm² | 5,9mA/cm² | 20,4mA/cm² | Unknown | 5,0mA/cm² |
| Maximum Power Density [W/cm²] (500Ω) | 7,9mW/cm² | 1,7mW/cm² | 6,5mW/cm² | Unknown | 39,9mW/cm² |
| Burst Mode (i.e., pulse trains): Pulses per burst | N/A | N/A | N/A | N/A | N/A |
| Burst Mode (i.e., pulse trains): Bursts per second | N/A | N/A | N/A | N/A | N/A |
| Burst Mode (i.e., pulse trains): Burst duration (seconds) | N/A | N/A | N/A | N/A | N/A |
| Burst Mode (i.e., pulse trains): Duty Cycle [Line (b) ÷ Line (c)] | N/A | N/A | N/A | N/A | N/A |
| ON Time [seconds] | 1 – 20s | 2 – 20s | 2 – 20s | Default 6s | Unknown |
| OFF Time [seconds] | 1 – 50s | 2 – 20s | 2 – 50s | Default 12s | Unknown |
| Additional features | N/A | N/A | N/A | N/A | N/A |

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## Functional Electrical Stimulation Programs:

| Characteristics/ Specifications | New Device | Predicate Device | New Device | Predicate Device | New Device | Predicate Device | New Device | Predicate Device |
|---|---|---|---|---|---|---|---|---|
| ***Basic Unit Chracteristics*** | | | | | | | | |
| Program | FES 1 Grasp/Release | Exercise Open | FES 2 Grasp/Release (EMG) | Exercise Open | FES 3 Open/Close | Exercise | FES 4 Open/Close (EMG) | Palmar Grasp |
| 510(k) Number | K060950 | K031900 | K060950 | K031900 | K060950 | K031900 | K060950 | K031900 |
| Manufacturer | Otto Bock | Ness | Otto Bock | Ness | Otto Bock | Ness | Otto Bock | Ness |
| Device Name | STIWELL med4 | Handmaster | STIWELL med4 | Handmaster | STIWELL med4 | Handmaster | STIWELL med4 | Handmaster |
| Power Source(s) | Battery Pack Li-Ion 11,1V | Battery Pack Ni Cd 9,6V | Battery Pack Li-Ion 11,1V | Battery Pack Ni Cd 9,6V | Battery Pack Li-Ion 11,1V | Battery Pack Ni Cd 9,6V | Battery Pack Li-Ion 11,1V | Battery Pack Ni Cd 9,6V |
| Method of Line Current Isolation | Medical Class II Power Adapter | N/A | Medical Class II Power Adapter | N/A | Medical Class II Power Adapter | N/A | Medical Class II Power Adapter | N/A |
| Leakage Current (normal condition) | N/A (Battery) | N/A | N/A (Battery) | N/A | N/A (Battery) | N/A | N/A (Battery) | N/A |
| Leakage Current (single fault cond.) | N/A (Battery) | N/A | N/A (Battery) | N/A | N/A (Battery) | N/A | N/A (Battery) | N/A |
| No. Output Mod. | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| No. Output Chan. | 3 | 2 | 3 | 2 | 3 | 5 | 3 | 5 |
| Stimulated Musc. | Wrist extensors Finger flexors Thumb flexor | Finger extensors Thumb extensor | Wrist extensors Finger flexors Thumb flexor | Finger extensors Thumb extensor | Finger/thumb extensors Finger flexors Thumb flexor – | Finger extensors Thumb extensor Finger flexors Thumb flexor Thenar muscle | Finger/thumb extensors Finger flexors Thumb flexor – | Finger extensors Thumb extensor Finger flexors Thumb flexor Thenar muscle |
| No. of EMG Chan. | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 |
| EMG sensitivity | N/A | N/A | 1µV | N/A | N/A | N/A | 1µV | N/A |
| EMG Sampl. Rate | N/A | N/A | 3kHz | N/A | N/A | N/A | 3kHz | N/A |
| EMG detection | N/A | N/A | Bipolar | N/A | N/A | N/A | Bipolar | N/A |
| EMG range (µV) | N/A | N/A | 1-2000µV | N/A | N/A | N/A | 1-2000µV | N/A |
| EMG bandwidth | N/A | N/A | 70-480Hz | N/A | N/A | N/A | 70-480Hz | N/A |
| EMG signal proc. | N/A | N/A | AVR | N/A | N/A | N/A | AVR | N/A |
| Synchr. or Altern.? | Alternating | Alternating | Alternating | Alternating | Alternating | Alternating | Alternating | Alternating |
| Meth. Chan. isol. | Transformer, Inductive couplers | Transformer, Opt isolator | Transformer, Inductive couplers | Transformer, Opt isolator | Transformer, Inductive couplers | Transformer, Opt isolator | Transformer, Inductive couplers | Transformer, Opt isolator |
| RC or RV? | Regulated Current | Regulated Voltage | Regulated Current | Regulated Voltage | Regulated Current | Regulated Voltage | Regulated Current | Regulated Voltage |
| Firmware/? | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| PC Software? | No | No | No | No | No | No | No | No |
| Aut. Overload Trip | Yes | Unknown | Yes | Unknown | Yes | Unknown | Yes | Unknown |
| Aut. No-Load Trip | Yes | Unknown | Yes | Unknown | Yes | Unknown | Yes | Unknown |
| Aut. Shut Off | Yes (10min) | No | Yes (10min) | No | Yes (10min) | No | Yes (10min) | No |
| Override Control? | Yes (Stop Button) | Yes | Yes (Stop Button) | Yes | Yes (Stop Button) | Yes | Yes (Stop Button) | Yes |
| Display: On/Off? | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Display: Low Batt? | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Display: V/C Level | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Timer Range | 15-60min | Max. 90min | 15-60min | Max. 90min | 15-60min | Max. 90min | 15-60min | Max. 45min |
| Compliance with Voluntary Standards? | IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 | Unknown | IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 | Unknown | IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 | Unknown | IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 | Unknown |
| Compliance with 21 CFR 898? | Yes | Unknown | Yes | Unknown | Yes | Unknown | Yes | Unknown |
| Weight | 440g | 685g | 440g | 685g | 440g | 685g | 440g | 685g |
| Dimensions (WxHxD) in [mm] | 175x95x30 | 172x91x40 (Control unit) | 175x95x30 | 172x91x40 (Control unit) | 175x95x30 | 172x91x40 (Control unit) | 175x95x30 | 172x91x40 (Control unit) |
| Housing Material and Construction | Plastics | Plastics | Plastics | Plastics | Plastics | Plastics | Plastics | Plastics |
| ***Output Specifications*** | | | | | | | | |
| Waveform | Biphasic symmetrical | Biphasic symmetrical | Biphasic symmetrical | Biphasic symmetrical | Biphasic symmetrical | Biphasic symmetrical | Biphasic symmetrical | Biphasic symmetrical |
| Shape | Rectangular | Sinusoidal | Rectangular | Sinusoidal | Rectangular | Sinusoidal | Rectangular | Sinusoidal |
| Maximum Output Voltage (500Ω) | 50V | 106V | 50V | 106V | 50V | 106V | 50V | 106V |
| Maximum Output Voltage (2kΩ) | 115V | 163V | 115V | 163V | 115V | 163V | 115V | 163V |
| Maximum Output Voltage (10kΩ) | N/A | Unknown | N/A | Unknown | N/A | Unknown | N/A | Unknown |
| Maximum Output Current (500Ω) | 100mA | 212mA | 100mA | 212mA | 100mA | 212mA | 100mA | 212mA |
| Maximum Output Current (2kΩ) | 58mA | 92mA | 58mA | 92mA | 58mA | 92mA | 58mA | 92mA |
| Maximum Output Current (10kΩ) | N/A | Unknown | N/A | Unknown | N/A | Unknown | N/A | Unknown |
| Pulse Width | 50-400µs | 100-350µs | 50-400µs | 100-350µs | 50-400µs | 100-350µs | 50-400µs | 100-500µs |
| Frequency [Hz] | 1-140Hz Default: 35Hz | 38Hz | 1-140Hz Default: 35Hz | 38Hz | 1-140Hz Default: 35Hz | 38Hz | 1-140Hz Default: 35Hz | 18Hz |
| Net Charge [µC per pulse]: (500Ω) | 0µC | 0µC | 0µC | 0µC | 0µC | 0µC | 0µC | 0µC |
| Maximum Phase Charge [µC] (500Ω) | 40µC | 75µC | 40µC | 75µC | 40µC | 75µC | 40µC | 106µC |
| Maximum Current Density [mA/cm²] (500Ω) | 12,5mA/cm² | 15,9mA/cm² | 12,5mA/cm² | 15,9mA/cm² | 12,5mA/cm² | 15,9mA/cm² | 12,5mA/cm² | 15,9mA/cm² |
| Maximum Power Density [W/cm²] (500Ω) | 7,9mW/cm² | 0,39 mW/cm² | 7,9mW/cm² | 0,39 mW/cm² | 7,9mW/cm² | 0,39 mW/cm² | 7,9mW/cm² | 0,39 mW/cm² |
| Burst Mode: Pulses per burst | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Burst Mode: Bursts per second | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Burst Mode: Burst duration (seconds) | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Burst Mode: Duty Cycle | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| ON Time [sec.] | 1 – 20s | Unknown | 1 – 20s | Unknown | 1 – 20s | Unknown | 1 – 20s | Trigger controlled |
| OFF Time [sec.] | 1 – 30s | Unknown | Trigger controlled (min. 1 – 30s) | Unknown | 1 – 30s | Unknown | Trigger controlled (min. 1 – 30s) | Trigger controlled |
| Additional features | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |

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Incontinence Programs:

| Characteristics/ Specifications | New Device | Predicate Device | New Device | Predicate Device | New Device | Predicate Device | New Device | Predicate Device |
|---|---|---|---|---|---|---|---|---|
| ***Basic Unit Chracteristics*** | | | | | | | | |
| Program | U1 Urge | P2, P3 Urge | U2 Stress | P1 Stress | U3 Mixed | P4 Mixed | U4 Feedback | EMG Script |
| 510(k) Number | K080950 | K032988 | K080950 | K032988 | K080950 | K032988 | K080950 | K053434 |
| Manufacturer | Otto Bock | Danmeter A/S | Otto Bock | Danmeter A/S | Otto Bock | Danmeter A/S | Otto Bock | Thought Technology Ltd. |
| Device Name | STIWELL med4 | Elpha 4 Conti | STIWELL med4 | Elpha 4 Conti | STIWELL med4 | Elpha 4 Conti | STIWELL med4 | Myotrac Infinity |
| Power Source(s) | Battery Pack Li-Ion 11,1V | Battery NMH or Alkaline 9V | Battery Pack Li-Ion 11,1V | Battery NMH or Alkaline 9V | Battery Pack Li-Ion 11,1V | Battery NMH or Alkaline 9V | Battery Pack Li-Ion 11,1V | Battery Pack NMH |
| Method of Line Current Isolation | Medical Class II Power Adapter | N/A | Medical Class II Power Adapter | N/A | Medical Class II Power Adapter | N/A | Medical Class II Power Adapter | Medical Class II Power Adapter |
| Leakage Current (normal condition) | N/A (Battery) | N/A (Battery) | N/A (Battery) | N/A (Battery) | N/A (Battery) | N/A (Battery) | N/A (Battery) | N/A (Battery) |
| Leakage Current (single fault cond.) | N/A (Battery) | N/A (Battery) | N/A (Battery) | N/A (Battery) | N/A (Battery) | N/A (Battery) | N/A (Battery) | N/A (Battery) |
| No. Output Mod. | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 |
| No. Output Chan. | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 |
| No. of EMG Chan. | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 |
| EMG sensitivity | N/A | N/A | N/A | N/A | N/A | N/A | 1µV | <0,1µV |
| EMG Sampl. Rate | N/A | N/A | N/A | N/A | N/A | N/A | 3kHz | 2,048kHz |
| EMG detection | N/A | N/A | N/A | N/A | N/A | N/A | Bipolar | Bipolar |
| EMG range (µV) | N/A | N/A | N/A | N/A | N/A | N/A | 1-2000µV | 0-2000µV |
| EMG bandwidth | N/A | N/A | N/A | N/A | N/A | N/A | 70-480Hz | 10Hz-1kHz |
| EMG signal proc. | N/A | N/A | N/A | N/A | N/A | N/A | AVR | RMS |
| Synchr. or Altern.? | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Meth. Chan. Isol. | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| RC or RV? | Regulated Current | Regulated Current | Regulated Current | Regulated Current | Regulated Current | Regulated Current | N/A | N/A |
| Firmware!? | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Aut. Overload Trip | Yes | Yes | Yes | Yes | Yes | Yes | N/A | N/A |
| Aut. No-Load Trip | Yes | Yes | Yes | Yes | Yes | Yes | N/A | N/A |
| Aut. Shut Off | Yes (10min) | Yes | Yes (10min) | Yes | Yes (10min) | Yes | Yes (10min) | Unknown |
| Override Control? | Yes (Stop Button) | Yes | Yes (Stop Button) | Yes | Yes (Stop Button) | Yes | Yes (Stop Button) | Yes |
| Display: On/Off? | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Display: Low Batt? | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Timer Range | 5 – 25min | 5 – 95min | 5 – 25min | 5 – 95min | 5 – 25min | 5 – 95min | 2-4min | 1-120min |
| Compliance with Voluntary Standards? | IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 | IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 | IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 | IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 | IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 | IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 | IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 | Unknown |
| Compliance with 21 CFR 898? | Yes | Unknown | Yes | Unknown | Yes | Unknown | Yes | Unknown |
| Weight | 440g | 158g | 440g | 158g | 440g | 158g | 440g | 330g |
| Dimensions (WxHxD) in [mm] | 175x95x30 | 114x60x31 | 175x95x30 | 114x60x31 | 175x95x30 | 114x60x31 | 175x95x30 | 102x152x51 |
| Housing Material and Construction | Plastics | Plastics | Plastics | Plastics | Plastics | Plastics | Plastics | Plastics |
| ***Output Specifications*** | | | | | | | | |
| Waveform | Biphasic symmetrical | Pulsed biphasic asymmetrical | Biphasic symmetrical | Pulsed biphasic asymmetrical | Biphasic symmetrical | Pulsed biphasic asymmetrical | N/A | N/A |
| Shape | Rectangular | Rectangular with discharge | Rectangular | Rectangular with discharge | Rectangular | Rectangular with discharge | N/A | N/A |
| Maximum Output Voltage (500Ω) | 50V | 50V | 50V | 50V | 50V | 50V | N/A | N/A |
| Maximum Output Voltage (2kΩ) | 115V | 150V | 115V | 150V | 115V | 150V | N/A | N/A |
| Maximum Output Voltage (10kΩ) | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Maximum Output Current (500Ω) | 100mA | 100mA | 100mA | 100mA | 100mA | 100mA | N/A | N/A |
| Maximum Output Current (2kΩ) | 58mA | 80mA | 58mA | 80mA | 58mA | 80mA | N/A | N/A |
| Maximum Output Current (10kΩ) | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Pulse Width | 500µs | 50-400µs | 300µs | 50-400µs | 350-500µs | 50-400µs | N/A | N/A |
| Frequency [Hz] | 10Hz | 1-10Hz | 35Hz | 20-80Hz | 5-60Hz | 1-80Hz | N/A | N/A |
| Net Charge [µC per pulse]: (500Ω) | 0µC | 0µC | 0µC | 0µC | 0µC | 0µC | N/A | N/A |
| Maximum Phase Charge [µC] (500Ω) | 50µC | 40µC | 30µC | 40µC | 60µC | 40µC | N/A | N/A |
| Surface area of the electrodes [$cm^2$] | Axel Goord (Surface) PR100 21,2$cm^2$ | Vaginal: 4,9$cm^2$ Anal: 3 $cm^2$ | Axel Goord (Surface) PR100 21,2$cm^2$ | Vaginal: 4,9$cm^2$ Anal: 3 $cm^2$ | Axel Goord (Surface) PR100 21,2$cm^2$ | Vaginal: 4,9$cm^2$ Anal: 3 $cm^2$ | N/A | N/A |
| Maximum Current Density [mA/$cm^2$] (500Ω) | 4,7 mA/$cm^2$ | *Vaginal:* 20,4mA/$cm^2$ *Anal:* 33,3mA/$cm^2$ | 4,7 mA/$cm^2$ | *Vaginal:* 20,4mA/$cm^2$ *Anal:* 33,3mA/$cm^2$ | 4,7 mA/$cm^2$ | *Vaginal:* 20,4mA/$cm^2$ *Anal:* 33,3mA/$cm^2$ | N/A | N/A |
| Maximum Power Density [W/$cm^2$] (500Ω) | 23,5 µW/$cm^2$ | *Vaginal:* 2,3mW/$cm^2$ *Anal:* 3,8mW/$cm^2$ | 105 µW/$cm^2$ | *Vaginal:* 2,3mW/$cm^2$ *Anal:* 3,8mW/$cm^2$ | 0,42 mW/$cm^2$ | *Vaginal:* 2,3mW/$cm^2$ *Anal:* 3,8mW/$cm^2$ | N/A | N/A |
| Burst Mode: Pulses per burst | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Burst Mode: Bursts per second | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Burst Mode: Burst duration (seconds) | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Burst Mode: Duty Cycle | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| ON Time [sec.] | 13s | 5-10s | 9-12s | 2-20s | 9-11s | 2-20s | N/A | N/A |
| OFF Time [sec.] | 3s | 1-5s | 7-9s | 2-20s | 3-6s | 2-20s | N/A | N/A |
| Additional features | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |

**Otto Bock Healthcare Products GmbH**
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HG WIEN FN 242378p · UID-Nr.: ATU 57529204 · ARA-Nr.: 8864 · ERA-Nr.: 50411
Bank Austria Creditanstalt Aktiengesellschaft, Filiale Westbahnstraße Swift Code: BKAUATWW BLZ 12 000, Konto-Nr. 09743146400
Erste Bank, Kommerzcenter Wien West 2 Swift Code: GIBAATWW BLZ 20 111, Konto-Nr. 30001045517

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TENS:

| Characteristics/ Specifications | New Device | Predicate Device | Predicate Device | Predicate Device |
|---|---|---|---|---|
| ***Basic Unit Chracteristics*** | | | | |
| 510(k) Number | K080950 | K032954 | K032954 | K940301 |
| Manufacturer | Otto Bock | Danmeter A/S | Danmeter A/S | Compex SA |
| Device Name, Model | STIWELL med4 | Elpho II1000 | Elpho II3000 | STIWELL med4 |
| Power Source(s) | Battery Pack Li-Ion 11,1V | Battery NiMH or Alkaline 9V | Battery Pack NiMH or Alkaline 9V | Battery Pack Li-Ion 11,1V |
| Method of Line Current Isolation | Medical Class II Power Adapter – Mascot (12,6VDC-15,1W) | N/A | N/A | Medical Class II Power Adapter – Mascot (12,6VDC-15,1W) |
| Patient Leakage Current (normal condition) | N/A (Battery) | N/A (Battery) | N/A (Battery) | N/A (Battery) |
| Patient Leakage Current (single fault condition) | N/A (Battery) | N/A (Battery) | N/A (Battery) | N/A (Battery) |
| Number of Output Modes | 1 | 1 | 1 | 1 |
| Number of Output Channels | 4 | 2 | 2 | 4 |
| Number of EMG (input) Channels | N/A | N/A | N/A | N/A |
| EMG sensitivity | N/A | N/A | N/A | N/A |
| EMG Sampling Rate | N/A | N/A | N/A | N/A |
| EMG detection (bipolar/ monopolar) | N/A | N/A | N/A | N/A |
| EMG range (µV) | N/A | N/A | N/A | N/A |
| EMG bandwidth | N/A | N/A | N/A | N/A |
| EMG signal processing (eg. RMS) | N/A | N/A | N/A | N/A |
| Synchronous or Alternating? | Alternating | Unknown | Unknown | Synchronous |
| Method of Channel Isolation | Transformer, Inductive couplers | Unknown | Unknown | Transformer |
| Regulated Current or Regulated Voltage? | Regulated Current | Regulated Current | Regulated Current | Regulated Current |
| Software/Firmware/ Microprocessor Control? | Yes | Yes | Yes | Yes |
| Automatic Overload Trip? | Yes | Yes | Yes | Yes |
| Automatic No-Load Trip? | Yes | Yes | Yes | Yes |
| Automatic Shut Off? | Yes (10min) | Yes | Yes | Unknown |
| Patient Override Control? | Yes (Stop Button) | Yes | Yes | Yes |
| Indicator Display: On/Off Status? | Yes | Yes | Yes | Yes |
| Indicator Display: Low Battery? | Yes | Yes | Yes | Yes |
| Indicator Display: Voltage/Current Level? | Yes | Yes | Yes | Yes |
| Timer Range (minutes) | 10 – 120min | -45min and cont. | 5 – 95min and cont. | 3 – 64min |
| Compliance with Voluntary Standards? (if yes, specify) | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-2-10 | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-2-10 | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-2-10 | Unknown |
| Compliance with 21 CFR 868? | Yes | Unknown | Unknown | Unknown |
| Weight | 440g | 168g | 158g | 420g |
| Dimensions (WxHxD) in (mm) | 175x95x30 | 117x60x31 | 114x60x31 | 148x80x30 |
| Housing Material and Construction | Plastics | Plastics | Plastics | Aluminium |
| ***Output Specifications*** | | | | |
| Waveform (e.g., pulsed monophasic, biphasic) | Biphasic symmetrical | Biphasic asymmetrical | Biphasic asymmetrical | Biphasic symmetrical |
| Shape (e.g., rectangular, spike, rectified sinusoidal) | Rectangular | Rectangular with discharge | Rectangular with discharge | Rectangular |
| Maximum Output Voltage (500Ω) | 50V | 20V | 50V | 50V |
| Maximum Output Voltage (2kΩ) | 115V | 76V | 164V | 200V |
| Maximum Output Voltage (10kΩ) | N/A | Unknown | Unknown | N/A |
| Maximum Output Current (500Ω) | 100mA | 40mA | 80mA | 100mA |
| Maximum Output Current (2kΩ) | 58mA | 38mA | 82mA | 100mA |
| Maximum Output Current (10kΩ) | N/A | Unknown | Unknown | N/A |
| Pulse Width (specify units) | 150µs, 200µs | 150µs, 180µs, 200µs | 50 – 400µs | Unknown |
| Frequency (Hz) | 2 – 100Hz | 2 – 120Hz | 0,5 – 150Hz | Unknown |
| For interferential modes only: Beat Frequency (Hz) | N/A | N/A | N/A | N/A |
| For multiphasic waveforms only: Symmetrical phases? | N/A | N/A | N/A | N/A |
| For multiphasic waveforms only: Phase Duration (including units); *state range,if applicable; both phases, if asymmetrical* | N/A | N/A | N/A | N/A |
| Net Charge [µC per pulse]; (500Ω) *If zero, state method of achieving zero net charge.* | 0µC<br>Same positive and negative impulse | 0µC<br>Output capacitor | 0µC<br>Output capacitor | 0µC<br>Same positive and negative impulse |
| Maximum Phase Charge (µC) (500Ω) | 20µC | 8µC | 24µC | Unknown |
| Maximum Current Density [mA/cm²] (500Ω) | 12,5mA/cm² | 2,1mA/cm² | 3,2mA/cm² | 5,0mA/cm² |
| Maximum Power Density (W/cm²) (500Ω) *using smallest electrode conductive surface area* | 1,0mW/cm² | 0,09mW/cm² | 1,4mW/cm² | Unknown |
| Burst Mode (i.e., pulse trains): Pulses per burst | 8 | 7 | 7 | Unknown |
| Burst Mode (i.e., pulse trains): Bursts per second | 2 | 2 | 0,5 – 5 | Unknown |
| Burst Mode (i.e., pulse trains): Burst duration (seconds) | 100ms | 87,5ms | 87,5ms | Unknown |
| Burst Mode (i.e., pulse trains): Duty Cycle [Line (b) x Line (c)] | 20% | 17,5% | 4,4% – 44% | Unknown |
| ON Time (seconds) | Continuous or Burst | Continuous or Burst | Continuous or Burst | Continuous |
| OFF Time (seconds) | N/A | N/A | N/A | N/A |
| Additional features (if applicable) | N/A | N/A | N/A | N/A |

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Erste Bank, Kommerzcenter Wien West 2 Swift Code: GIBAATWW BLZ 20 111, Konto-Nr. 30001045517

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Biofeedback:

| Characteristics/ Specifications | New Device | Predicate Device | Predicate Device |
|---|---|---|---|
| ***Basic Unit Chracteristics*** | | | |
| 510(k) Number | K080950 | K053434 | K040849 |
| Manufacturer | Otto Bock | Thought Technology Ltd. | Mentamove North America, LCC |
| Device Name, Model | STIMELL med4 | Myotrac Infinity | Mentamove |
| Power Source(s) | Battery Pack Li-Ion 11,1V | Battery Pack NiMH rechargeable | Battery Pack NiMH rechargeable |
| Method of Line Current Isolation | Medical Class II Power Adapter – Mascot (12,6VDC-15,1W) | Medical Class II Power Adapter (6VDC-15W) | Battery Charger (6VDC-2,1W) |
| Patient Leakage Current (normal condition) | N/A (Battery) | N/A (Battery) | N/A (Battery) |
| Patient Leakage Current (single fault condition) | N/A (Battery) | N/A (Battery) | N/A (Battery) |
| Number of Output Modes | 1 | 0 | 0 |
| Number of Output Channels | 1 | 0 | 0 |
| Number of EMG (input) Channels | 2 | 2 | 1 |
| EMG sensitivity | 1µV | <0,1µV | 1µV |
| EMG Sampling Rate | 3kHz | 2,048kHz | Unknown |
| EMG detection (bipolar/ monopolar) | Bipolar | Bipolar | Bipolar |
| EMG range (µV) | 1-2000µV | 0-2000µV | 2-2000µV |
| EMG bandwidth | 70-480Hz | 10Hz-1kHz | Unknown |
| EMG signal processing (eg. RMS) | AVR (Average Rectified Value) | RMS (Root Mean Square) | Unknown |
| Synchronous or Alternating? | N/A | N/A | N/A |
| Method of Channel Isolation | N/A | N/A | N/A |
| Regulated Current or Regulated Voltage? | N/A | N/A | N/A |
| Software/Firmware/ Microprocessor Control? | Yes | Yes | Yes |
| Automatic Overload Trip? | N/A | N/A | N/A |
| Automatic No-Load Trip? | N/A | N/A | N/A |
| Automatic Shut Off? | Yes (10min) | Unknown | Unknown |
| Patient Override Control? | Yes (Stop Button) | Yes | Yes |
| Indicator Display: On/Off Status? | Yes | Yes | Yes |
| Indicator Display: Low Battery? | Yes | Yes | Yes |
| Indicator Display: Voltage/Current Level? | N/A | N/A | N/A |
| Timer Range (minutes) | 5-30min | 1-120min | Unknown |
| Compliance with Voluntary Standards? (if yes, specify) | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-2-10 | Unknown | Unknown |
| Compliance with 21 CFR 898? | Yes | Unknown | Unknown |
| Weight | 440g | 330g | Unknown |
| Dimensions (WxHxD) in (mm) | 175x95x30 | 102x152x51 | Unknown |
| Housing Material and Construction | Plastics | Plastics | Plastics |
| ***Output Specifications*** | | | |
| Waveform (e.g., pulsed monophasic, biphasic) | N/A | N/A | N/A |
| Shape (e.g., rectangular, spike, rectified sinusoidal) | N/A | N/A | N/A |
| Maximum Output Voltage (500Ω) | N/A | N/A | N/A |
| Maximum Output Voltage (2kΩ) | N/A | N/A | N/A |
| Maximum Output Voltage (10kΩ) | N/A | N/A | N/A |
| Maximum Output Current (500Ω) | N/A | N/A | N/A |
| Maximum Output Current (2kΩ) | N/A | N/A | N/A |
| Maximum Output Current (10kΩ) | N/A | N/A | N/A |
| Pulse Width (specify units) | N/A | N/A | N/A |
| Frequency (Hz) | N/A | N/A | N/A |
| For interferential modes only: Beat Frequency (Hz) | N/A | N/A | N/A |
| For multiphasic waveforms only: Symmetrical phases? | N/A | N/A | N/A |
| For multiphasic waveforms only: Phase Duration (including units); | N/A | N/A | N/A |
| Net Charge (µC per pulse); (500Ω) | N/A | N/A | N/A |
| Maximum Phase Charge (µC) (500Ω) | N/A | N/A | N/A |
| Maximum Current Density [mA/cm$^2$] (500Ω) | N/A | N/A | N/A |
| Maximum Power Density [W/cm$^2$] (500Ω) | N/A | N/A | N/A |
| Burst Mode (i.e., pulse trains): Pulses per burst | N/A | N/A | N/A |
| Burst Mode (i.e., pulse trains): Bursts per second | N/A | N/A | N/A |
| Burst Mode (i.e., pulse trains): Burst duration (seconds) | N/A | N/A | N/A |
| Burst Mode (i.e., pulse trains): Duty Cycle [Line (b) x Line (c)] | N/A | N/A | N/A |
| ON Time [seconds] | N/A | N/A | N/A |
| OFF Time [seconds] | N/A | N/A | N/A |
| Additional features (if applicable) | N/A | N/A | N/A |

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## G Functional and Safety Testing:

Tests have been carried out according to the following standards:

| No. | Title | Version | Comments |
|---|---|---|---|
| IEC 60601-1 | Medical electrical equipment<br>Part 1: General requirements for safety | 1996-03 | Medical electrical devices<br>(Testing) |
| IEC 60601-1-1 | Medical electrical equipment<br>Part 1-1: General requirements for safety – Safety requirements for medical electrical systems | 2002-09-01 | Medical electrical devices<br>(Testing) |
| IEC 60601-1-2 | Medical electrical equipment<br>Part 1-2: General requirements for safety –Electromagnetic compatibility – requirements and tests | 2001 | EMC<br>(Testing) |
| IEC 60601-1-4 | Medical electrical equipment<br>Part 1-4: General requirements for safety – Programmable electrical medical systems | 2001-06-01 | Programmable Systems |
| IEC 60601-2-10 | Medical electrical equipment<br>Part 2-10: Particular requirements for the safety of nerve and muscle stimulators | 2003-04 | Medical electrical devices; EMC<br>(Testing) |
| IEC 721-3-2 | Classification of Environmental Conditions Part 3-2: Classes of Influencing Factors - Transport | 1981 | Transport<br>(Testing) |
| ISO 2248 | Packaging - Complete, filled transport packages - Vertical impact test by dropping | 1985 | Transport<br>(Testing) |
| ISO 2876 | Packaging - Complete, filled transport packages – Rolling test | 1985 | Transport<br>(Testing) |
| IEC 60512-8 | Electromechanical components for electronic equipment; basic testing procedures and measuring methods Part 8: Connector test (mechanical) and mechanical test on contacts and terminations | 3.0/1994-05 | Specific sections were used for verification testing |
| IEC 60512-9 | Electromechanical components for electronic equipment; basic testing procedures and measuring methods Part 9: Miscellaneous tests | 2.0/1992-05 | Specific sections were used for verification testing |
| IEC 68-1<br>+Corr.+A1 | Environmental testing<br>Part 1: General and Guidance | 1998 | Specific sections were used for verification testing |
| IEC 68-2-1<br>+A1+A2 | Environmental testing<br>Part 2-1: Tests, Tests A: Cold | 1994 | Specific sections were used for verification testing |

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| No. | Title | Version | Comments |
|---|---|---|---|
| IEC 68-2-2 +IEC68-2-2A+A2 | Environmental testing Part 2-2: Tests, Tests B: Dry heat | 1994 | Specific sections were used for verification testing |
| IEC 68-2-30 | Environmental testing - Part 2-30: Tests - Test Db: Damp heat, cyclic (12 h + 12 h cycle) | 2000 | Specific sections were used for verification testing |
| IEC 68-2-33 | Environmental testing - Part 2-33: Tests. Guidance on change of temperature tests | 2000 | Specific sections were used for verification testing |
| IEC 68-2-36 | Environmental testing Part 2-36, Tests Fdb: Vibrations, noise (broadband), repeatability: medium | 1973 | Specific sections were used for verification testing |
| IEC 68-2-78 | Environmental testing Part 2-78: Tests, Test Cb: Damp heat, steady state, primarily intended for devices | 2001 | Specific sections were used for verification testing |
| 21 CFR 898 | Performance Standard for electrode lead wires and patient cables | 1997 | Electrical safety (Testing) |

In addition to tests according to the above mentioned standards several functional and safety tests defined by the manufacturer have been conducted.

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## H Indications for use:

The STIWELL med4 is a neuromuscular electronic stimulator indicated for use under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions.

As a powered muscle stimulator the STIWELL med4 is indicated for the following conditions:

- Relaxation of muscle spasm
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion

As a transcutaneous electrical nerve stimulator for pain relief the STIWELL med4 is indicated for the following conditions:

- Symptomatic relief and management of chronic (long-term), intractable pain
- Adjunctive treatment in the management of post-surgical pain and post traumatic acute pain

As a biofeedback device the STIWELL med4 is indicated for the following conditions:

- Biofeedback, relaxation and muscle re-education purposes

As an external functional neuromuscular stimulator the STIWELL med4 is indicated for the following conditions:

- Helps to relearn voluntary motor functions of the extremities

As a nonimplanted electrical continence device the STIWELL med4 is indicated for the following conditions:

- Acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detruser muscles through reflexive mechanisms and strengthening of pelvic floor muscles
- Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal and the gluteus muscles

## I Conclusion:

The STIWELL med4 stimulation device is safe and effective for its intended use. The STIWELL med4 is substantially equivalent to the predicate devices.

## J Date summary submitted:

21st January 2008

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Otto Bock, Austria GmbH
% W.F. Jackson Associates, Ltd
Mr. William Jackson
2247 Jennifer Lane
North St. Paul, Minnesota 55109-2851

APR - 2 2009

Re: K080950
Trade/Device Name: STIWELL med4
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: IPF, GZI, KPI, GZJ, HCC
Dated: March 2, 2009
Received: March 25, 2009

Dear Mr. Jackson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

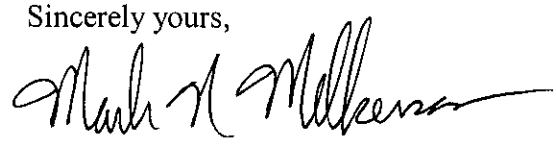
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

**510(k) Number (if known):** **K080950**

**Device Name:** STIWELL med4

**Indications for Use:**

The STIWELL med4 is a neuromuscular electronic stimulator indicated for use under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions.

As a powered muscle stimulator the STIWELL med4 is indicated for the following conditions:

- Relaxation of muscle spasm
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- Acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detruser muscles through reflexive mechanisms and strengthening of pelvic floor muscles
- Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal and the gluteus muscles

Prescription Use _X_ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDHR, Office of Device Evaluation (ODE)

Mark A. Milhorn

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K080950